

### **REMARKS**

This responds to the Office Action dated April 18, 2006. Claims 1 and 36 are amended. No claims are canceled. Claims 37-48 are added. As a result, claims 1-48 are now pending in this application.

#### **§112 Rejection of the Claims**

Claim 36 was rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Applicant has amended claim 36 to recite “The method of claim 19, further comprising introducing a catheter for at least one of the transmitting the acoustic energy and the receiving the acoustic energy.” Thus, Applicant believes claim 36 to be definite, and Applicant respectfully requests removal of this rejection.

#### **§102 Rejection of the Claims**

Claims 1-6 and 16-17 were rejected under 35 U.S.C. § 102(b) for anticipation by Siegel (U.S. Patent No. 5,062,841). Applicant respectfully traverses.

Applicant cannot find in the cited portions of Siegel any disclosure of a biocompatible body, wherein the at least a portion of the body is sized and shaped such that the change in the physical property is detectable using acoustic energy, as presently similarly recited or incorporated in claims 1-6 and 16-17. Instead, Siegel apparently merely discloses a glucose sensitive water-swellaable hydrogel member located within a housing 1, with Siegel’s device configured such that a difference in pressure between the inside of Siegel’s housing 1 and the patient’s body causes insulin to be pushed out from the housing 1 and into the body of the patient. (*See, e.g.*, Siegel column 4 lines 29-35). Siegel utterly fails to disclose that its swellaable member changes to an extent such that it is capable of being detected by acoustic energy. Instead, the Office Action states:

Examiner takes the position that change in size due to swelling, is inherently detectable by the use of acoustic energy.

(Office Action ¶ 4.) The Office Action failed to provide any reasoning for this assertion of inherency, and Appellant respectfully disagrees with this assertion. Appellant respectfully submits that the Office Action has not established a *prima facie* case of inherency because, as

recited in MPEP § 2112, "In relying upon the theory of inherency, the examiner must provide basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art," citing Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). First, nothing in Siegel explains how its swellable member will change to an extent that would be capable of being detected by acoustic energy with adequate signal-to-noise ratio to discern such a change. Second, Applicant respectfully submits that it is not at all apparent that Siegel's swellable member could be detected by an acoustic energy source because Siegel's swellable member is located inside of a housing 1. Applicant respectfully submits that the housing 1 of Siegel will inhibit transmission of acoustic energy to the swellable member, and Siegel certainly has not disclosed using an ultrasound source located within the housing 1 to detect a change in size of the swellable member. Moreover, because Siegel's swellable member is within a housing 1, it is necessarily not in contact with tissue as recited or incorporated in the present claims.

Because Siegel apparently does not expressly or inherently disclose all elements presently recited or incorporated in claims 1-6 and 16-17, Applicant respectfully submits that no *prima facie* case of anticipation presently exists with respect to these claims. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

#### §103 Rejection of the Claims

Claims 1-33 and 35 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Altman et al. (U.S. Patent No. 6,296,630) in view of Lew et al. (U.S. 2003/0100822) and further in view of Siegel (U.S. Patent No. 5,062,841) as applied above. Applicant respectfully traverses.

#### Concerning claims 1-17:

Applicant cannot find in the cited portions of the cited references any disclosure, teaching, or suggestion of a biocompatible body, wherein at least a portion of the body is sized and shaped such that the change in the physical property is detectable using acoustic energy, as presently recited or incorporated in these claims. The Office Action states:

In regards to claim 1, Examiner takes the position that hydrogel membrane that makes of the patch as taught by Altman et al. would be inherently capable of having at least one physical property change (swelling in size) in response to a physiological condition, such as an increase in blood glucose level since it is

known that hydrogels have the characteristic, as taught by Siegel (col. 3 lines 51-56).

(Office Action at 4.) Applicant respectfully disagrees. The Office Action failed to provide any reasoning for this assertion of inherency, and Appellant respectfully disagrees with this assertion. Appellant respectfully submits that the Office Action has not established a *prima facie* case of inherency because, as recited in MPEP § 2112, "In relying upon the theory of inherency, the examiner must provide basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art," citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). Applicant respectfully submits that nothing in Altman, Lew, or Siegel discloses a swellable member that will necessarily change to an extent that would be capable of being detected by acoustic energy with adequate signal-to-noise ratio to discern such a change. By contrast, the present claims recite or incorporate "at least a portion of the body is sized and shaped such that the change in physical property is detectable using acoustic energy." Applicant respectfully submits that not all bodies that change size will do so to an extent that is practicably detectable using acoustic energy, and nothing in any of the Altman, Lew, or Siegel references specifically discloses a body that is sized and shaped such that the change in the physical property is actually detectable using acoustic energy. Accordingly, because all elements recited or incorporated in claims 1-17 are not expressly or inherently disclosed, taught, or suggested by Altman, Lew and/or Siegel, Applicant respectfully submits that no *prima facie* case of obviousness presently exists with respect to these claims. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Concerning claim 18:

Applicant cannot find in the cited portions of the cited references any disclosure, teaching, or suggestion of spheres (or anything else) sized and shaped to be disposed "within" a myocardium of a subject, as recited in this claim. The Office Action asserts:

Altman et al. teaches of an implantable cardiac drug delivery system for delivery agents to be introduced within a myocardium of a subject (col. 9 lines 32-35), comprising a delivery patch or patches that may consist of a hydrogel (col. 12 lines 11-13), a catheter (col. 7 lines 56-61, and the use of an acoustic transmitter (col. 20 lines 39-43).

(Office Action ¶ 6.) Applicant respectfully disagrees with any assertion that Altman discloses, teaches, or suggests disposing spheres (or anything else) “within” a myocardium of a subject.

For example, the first cited portion of Altman merely states:

One embodiment for extremely local delivery of agents to the myocardium involves a penetrating structure that has a fluid pathway to a depth within the myocardium for local infusion of pharmacological agents on demand.

(Altman at col. 9, lines 32-35.) This, however, merely relates to a penetrating structure across the myocardium for infusing a fluid into the myocardium, rather than to inserting an acoustically detectable object “within” a myocardium as recited in claim 18. Similarly, the second cited portion of Altman merely states:

Alternatively, the barrier could be a thin hydrogel or other material through which the delivery would be required to diffuse more slowly.

(Altman at col. 12, lines 11-13.) Applicant respectfully submits that nothing in this cited passage of Altman indicates locating a hydrogel within a myocardium. Likewise, the third cited portion of Altman merely states:

Drugs or other anti-arrhythmia agents may be delivered into one or more regions of the atrial or ventricular wall to control arrhythmia of the atrium or ventricle with devices implanted into the chest, including a drug delivery catheter with a tip for implantation into the heart wall and a drug reservoir implanted in the chest.

(Altman at col. 7, lines 56-61.) Applicant respectfully submits that because this cited passage apparently discusses an infusion catheter with a tip in the heart wall and other end connected toward a drug reservoir implanted in the chest, it actually teaches away from disposing an acoustically detectable sphere “within” a myocardium of a subject. Moreover, Applicant can find nothing in Lew and/or Siegel to overcome this deficiency in Altman.

Accordingly, because all elements recited in claim 18 are apparently not disclosed, taught, or suggested by Altman, Lew and/or Siegel, Applicant respectfully submits that no *prima facie* case of obviousness presently exists with respect to this claim. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of this claim.

Concerning claims 19-36:

Applicant cannot find in the cited portions of the cited references any disclosure, teaching, or suggestion of introducing at least one body into contact with a tissue, wherein the

body includes at least one physiological property that changes in response to a physiological change associated with the tissue, transmitting the acoustic energy to the body and the tissue, receiving transmitted acoustic energy for detecting a change in the physical property of the body, and detecting the physiological change by detecting the change in the physical property of the body, as recited or incorporated in these claims.

For example, the only cited portion of any of Altman, Lew, and/or Siegel that mentions acoustic energy is the following cited passage from Altman:

Other examples include distally located electrically activated piezoelectric crystals or electrodes to act as energy sources for drug delivery for improving the transport into cells, distally located ultrasound transducer for implantation using ultrasound imaging.

(Altman at col. 20, lines 39-43.) Applicant respectfully submits that nothing in this cited passage discloses, teaches, or suggests detecting a physiological change by detecting a change in the physical property of a body introduced into contact with tissue. Instead, the cited passage apparently merely relates to using ultrasonic imaging to help implant an infusion catheter.

Accordingly, because all elements recited or incorporated in claims 19-36 are apparently not disclosed, taught, or suggested by Altman, Lew and/or Siegel, Applicant respectfully submits that no *prima facie* case of obviousness presently exists with respect to these claims. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Allowable Subject Matter

Claim 34 was indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Nonetheless, because claim 34 incorporates all of the language of independent claim 19, Applicant respectfully submits that claim 34 is allowable in its present form for the reasons discussed above with respect to claim 19. Accordingly, Applicant respectfully requests allowance of claim 34.

*New Claims*

Applicant has added new claims 37-48, which Applicant respectfully submits are fully supported by the specification as filed, and allowable. Applicant respectfully requests allowance of new claims 37-48.

*Reservation of Rights; References Not Relied Upon*

Applicant need not address the references that were made of record but not relied upon as a basis of rejection. Applicant does not admit that the references are prior art or applicable against the present claims, and Applicant reserves the right to address such references if they are subsequently made a basis of rejection. Applicant reserves the right to swear behind any references that are cited in a rejection under 35 U.S.C. 102(a), 102(e), 103/102(a), and 103/102(e), such as provided under 37 C.F.R. § 1.131, or otherwise. Statements distinguishing the claimed subject matter over the cited documents are not to be interpreted as admissions that the documents used as references are prior art. Applicant further submits that the pending dependent claims include further patentable subject matter, and Applicant reserves all rights to present later arguments as to the patentability of such dependent claims.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

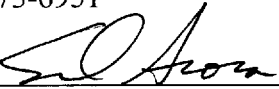
Respectfully submitted,

ROBERT J. SWEENEY ET AL.

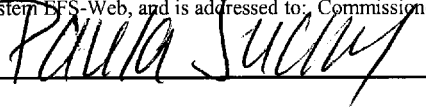
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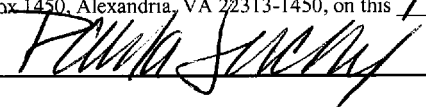
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Date July 17, 2006

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17 day of June, 2006.

  
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